

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

SEAGEN INC.,

Plaintiff,

V.

DAIICHI SANKYO CO., LTD.,

Defendant,

ASTRAZENECA PHARMACEUTICALS
LP, and ASTRAZENECA UK LTD

Intervenor-Defendants.

CIVIL ACTION NO. 2:20-CV-00337-JRG

ORDER ON PRETRIAL MOTIONS AND MOTIONS *IN LIMINE*

The Court held a Pretrial Conference in the above-captioned matter on Thursday, February 24, 2022 and Friday, February 25, 2022 regarding pending pretrial motions and motions *in limine* (“MILs”) filed by Plaintiff Seagen Inc. (“Plaintiff” or “Seagen”) and Defendants Daiichi Sankyo Co., Ltd. (“DSC”) and AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. (collectively, “AZ”) (DSC together with AZ, the “Defendants”) (Seagen together with Defendants, the “Parties”). (Dkt. Nos. 252, 253, 255, 262, 267, 308, 314, 315, 319, 325). This Order memorializes the Court’s rulings on the aforementioned pretrial motions and MILs as announced into the record, including additional instructions that were given to the Parties. Although this Order summarizes the Court’s rulings as announced into the record during the pretrial hearing, this Order in no way limits or constrains such rulings from the bench. Accordingly, it is hereby **ORDERED** as follows:

PRETRIAL MOTIONS

1. Defendants' Motion for Summary Judgment of Anticipation (Dkt. No. 255)

The motion was **DENIED**. (Dkt. No. 343 at 53:3–15). The Court found that the motion turned on issues of priority date and written description, which under *Ariad Pharms. Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) and various other authorities are questions of fact that should be resolved by the jury.

2. Seagen's Motion to Strike Portions of the Expert Reports of John M. Lambert (Dkt. No. 252)

The motion was **GRANTED** with respect to issues related to proceedings before the European Patent Office. (Dkt. No. 343 at 80:1–10). The Court found that these issues were likely to be confusing and struck Paragraphs 18, 81, 341 of Dr. Lambert's Opening Report and paragraph 148 of Dr. Lambert's Responsive Report. The motion was **DENIED** as to the remaining portions thereof. (*Id.* at 78:21–79:25, 80:10–11).

3. Seagen's Motion to Strike the Second Expert Report of David Manspeizer and Any Reliance thereon by DSC Witnesses (Dkt. No. 253)

The motion was **GRANTED**. (*Id.* at 82:17–83:18). The Court struck Mr. Manspeizer's Responsive Report in its entirety for the purposes of the jury trial. His opinions therein relate solely to prosecution laches which may be presented at a subsequent bench trial (should one be needed). The Court found that Mr. Manspeizer's opinions were not relevant to issues that the jury will be asked to decide and also that there was a high risk of jury confusion to be avoided pursuant to FRE 403.

4. Seagen's Renewed Motion for Sanctions (Dkt. No. 267)

The motion was **GRANTED-IN-PART** with respect to Seagen's request for monetary sanctions. (*Id.* at 94:23–96:18). The Court ordered DSC to pay Seagen \$75,000 as a partial reimbursement for Seagen's costs to bring the various motions to compel on the issue as a sanction

for DSC's discovery conduct. The Court found that DSC violated its disclosure obligation and breached its discovery responsibility in this case, and accordingly, sanctions were warranted. The Court **DENIED** the motion with respect to Seagen's request for a related jury instruction. (*Id.*).

5. Defendants' Motion for Sanctions (Dkt. No. 308)

The motion was **DENIED**. (*Id.* at 106:13–107:22). The Court found that Seagen's description of the notebooks was consistent with that disclosed on the record in open court. The Court also noted that if DSC had timely produced these notebooks, such discussions would not have occurred in open court. The Court found the conduct complained of by DSC to be substantially of their own making.

6. Seagen's Motion for Leave to use Certain Documents Produced by DSC in Co-Pending Proceeding (Dkt. No. 262)

The motion was **DENIED-AS-MOOT**. (*Id.* at 107:23–25).

MOTIONS *IN LIMINE*¹

It is **ORDERED** that the Parties, their witnesses, and counsel shall not raise, discuss, or argue the following before the venire panel or the jury without prior leave of the Court:

I. AGREED MOTIONS *IN LIMINE* (Dkt. Nos. 315, 325)

The following MILs 1–13 in the Parties’ Joint Notices (Dkt. Nos. 315, 325) were **GRANTED AS AGREED** (Dkt. No. 343 at 108:17–109:4):

<u>Agreed MIL 1</u>	Preclude questioning, testimony, evidence, arguments or efforts to malign based on religious or political beliefs, race, ethnicity, gender, national origin, geographic location, sexual orientation, or health (including COVID-19 vaccination status) of a party, witness, attorney, or law firm, or commenting on related topics including political issues/leanings and the COVID-19 pandemic, or any party being a vaccine manufacturer.
<u>Agreed MIL 2</u>	Preclude questioning, testimony, evidence, or arguments referring to net worth of any witness or the size, total revenue, total profits, or market cap of the Parties.
<u>Agreed MIL 3</u>	Preclude questioning, testimony, evidence, or arguments regarding PTAB proceedings involving the ’039 Patent.
<u>Agreed MIL 4</u>	Preclude questioning, testimony, evidence, or arguments referring to Seagen as being “greedy” or any other pejorative synonyms.
<u>Agreed MIL 5</u>	Preclude questioning, testimony, evidence, or arguments suggesting that there is anything legally improper in filing a patent application or writing patent claims to cover a competitor’s product.
<u>Agreed MIL 6</u>	Preclude questioning, testimony, evidence, or arguments solely regarding prosecution laches or any other equitable issues from the jury trial.
<u>Agreed MIL 7</u>	Preclude questioning, testimony, evidence, or arguments suggesting or stating that any result of this case would or could have an effect on Enhertu®, such as removing Enhertu® from the market, making Enhertu® unavailable to patients, taking Enhertu away from patients

¹ As a general matter, the Court noted that MILs should not be used as a back-door motion to strike expert opinions or *Daubert* motion. The motion *in limine* process is not a substitute for *Daubert* motions or motions to strike portions of an expert’s report, and unless expressly stated otherwise, the Court will not use MILs to circumscribe an expert’s report that has survived *Daubert* motions and motions to strike. (Dkt. No. 343 at 157:16–158:14)

currently taking Enhertu®, increasing the cost of Enhertu, or decreasing access to Enhertu.

Agreed MIL 8 No arguments, evidence, or reference to the relevant legal standards as applied under other civil or criminal cases except to the extent described in the jury instructions.

Agreed MIL 9 Preclude any attorney argument, evidence, testimony, insinuation, reference, or assertions regarding a witness' choice to testify in his or her native or chosen language.

Agreed MIL 10 No arguments or reference suggesting that Enhertu® infringes any Seagen non-asserted patents or patent applications.

Agreed MIL 11 Preclude evidence and argument bolstering or disparaging the U.S. Patent Office, its examiners, or the process for prosecuting patent applications or granting patents in the United States. This does not preclude evidence and argument consistent with the Federal Judiciary Center patent video played to the jury or regarding the facts in the prosecution history of the '039 Patent or patent family.

Agreed MIL 12 Preclude argument or reference to any pre-trial disputes or rulings over discovery, alleged failure or refusal to provide requested discovery, or any witness or party's discovery conduct without prior approval from the Court.

Agreed MIL 13 Preclude argument or reference to pre-trial disputes over venue, including any motion to transfer or dismiss venue in the Eastern District of Texas on the part of Defendants and any judicial ruling regarding venue. This does not preclude testimony, evidence, or argument as to the underlying facts regarding venue or personal jurisdiction.

II. PLAINTIFF'S OPPOSED MOTIONS *IN LIMINE* (Dkt. No. 314)

Plaintiff's MIL 1 Preclude Defendants from introducing or eliciting testimony, evidence, or argument about work on new ADC technologies after the 2004 effective filing date of the '039 Patent for invalidity purposes.

The MIL was **DENIED**. (Dkt. No. 343 at 115:16–20). The Court noted that, consistent with its prior rulings, the jury will properly decide the disputed priority date.

Plaintiff's MIL 2 **Preclude AZ from introducing or eliciting any evidence at trial beyond evidence relating to its marketing DS-8201 under the Enhertu® brand in the U.S.**

The MIL was **DENIED**. (*Id.* at 117:4–119:13). The Court noted that for the purposes of trial there will be two distinct sides in this case: DSC and AZ will be on one side and Seagen will be on the other. Further, each side will have an opportunity to put on witnesses but there will not be any duplication or overt delineation between the Defendants, including AZ.

Plaintiff's MIL 3 **Preclude Defendants from introducing or eliciting any testimony, evidence, or argument about European prosecution of patents related to the '039 Patent.**

The MIL was **GRANTED-AS-AGREED**. (*Id.* at 110:24–111:8).

Plaintiff's MIL 4 **Preclude Defendants from introducing or eliciting any testimony, evidence, or argument regarding Seagen's motives for bringing and prosecuting this action, including any suggestion that Seagen is attempting to exert market pressure on DSC or AZ, or improperly use the judicial system or litigation as an anti-competitive tool.**

The MIL was **DENIED-AS-MOOT** per the Parties' agreement. (*Id.* at 111:10–23).

Plaintiff's MIL 5 **Preclude testimony, evidence, or argument disparaging the U.S. patent office, its examiners, or the patent process.**

The MIL was **DENIED-AS-MOOT** per the Parties' agreement on Agreed MIL 11. (*Id.* at 119:16–25; Dkt. No. 325).

Plaintiff's MIL 6 **Preclude Defendants from presenting improperly disclosed testimony, evidence, or argument on research and development of DS-8201.**

The MIL was **DENIED**. (Dkt. No. 343 at 125:19–126:11).

Plaintiff's MIL 7 **Preclude Defendants from introducing any testimony, evidence, or argument that DSC owns patents or patent applications covering the accused product (DS-8201/Enhertu), or that AZ has licensed any such patents or patent applications.**

The MIL was **GRANTED-AS-AGREED**. (*Id.* at 112:1–12).

Plaintiff's MIL 8 **Preclude Defendants from introducing any questioning, testimony, evidence, or argument suggesting that Seagen's '039 Patent does not cover any Seagen marketed products.**

The MIL was **GRANTED-AS-AGREED**. (*Id.* at 113:15–114:11). Per the Parties' agreement announced into the record, Defendants will not present argument, testimony, or evidence that Seagen must practice the '039 Patent for there to be infringement, or for Seagen to be entitled to lost profits. The MIL does not prohibit Defendants from presenting arguments, evidence, or testimony about Seagen not having a marketed product within the scope of the claims. (*Id.*).

Plaintiff's MIL 9 **Preclude questioning, testimony, evidence, or arguments about whether Seagen "invented" anything other than what is claimed in the '039 Patent.**

The MIL was **GRANTED**. (*Id.* at 129:11–130:11). The Court noted that it would be an active gatekeeper in this context. Each Party must seek and obtain advance leave from the Court before traversing the topics covered by this MIL.

Plaintiff's MIL 10 **Preclude questioning, testimony, evidence, or arguments suggesting or stating that any result of this case would or could have an effect on patients or that patients would be harmed if Enhertu were removed from the market.**

The MIL was **DENIED-AS-MOOT** per the Parties' agreement on Agreed MIL 7. (*Id.* at 114:14–17; Dkt. No. 315).

III. DEFENDANTS' OPPOSED MOTIONS *IN LIMINE* (Dkt. No. 319)

Defendants' MIL 1 **Plaintiff should be precluded from introducing evidence of or referring to Daiichi Sankyo Japan's alleged copying of technology in the public**

domain, including conjugating a drug linker to a cysteine and methods for conjugating antibodies to drug-linkers.

The MIL was **GRANTED**. (Dkt. No. 343 at 153:3–11). The Court noted that the MIL prohibits evidence of copying technology that was in the public domain, without prior leave of the Court.

Defendants’ MIL 2 **Plaintiff should be precluded from introducing evidence of or referring to Daiichi Sankyo Japan’s alleged copying of subject matter that is not an embodiment of the claims.**

The MIL was **DENIED**. (*Id.* at 155:1–156:2). The Court noted that denial of this MIL does not preclude Defendants from objecting to evidence it believes is irrelevant or otherwise violates the Federal Rules of Evidence.

Defendants’ MIL 3 **Plaintiff should be precluded from introducing evidence or suggesting that Daiichi Sankyo Japan’s alleged copying prior to issuance of the asserted patent (and/or the filing of the application that led to the ’039 Patent) can form a basis of liability for patent damages and/or willful infringement.**

The MIL was **GRANTED**. (*Id.* at 156:9–23). The Court noted that it will be an active gatekeeper and, as with all *limine* matters, this MIL should not be interpreted as an absolute prohibition on all evidence in this category. Rather, Seagen must seek and obtain advance leave of Court before traversing topics covered by this MIL.

Defendants’ MIL 4 **Preclude any reference to the prior Seagen and Daiichi Sankyo Japan collaboration.**

The MIL was **DENIED**. (*Id.* at 156:24–157:15).

Defendants’ MIL 5 **Preclude any reference or characterizations of “stealing,” “copying,” “misappropriating,” “pirating,” “trespassing,” or any similar terms.**

The MIL was **GRANTED-AS-AGREED** with respect to “misappropriation” and “pirating.” (*Id.* at 159:5–14). The MIL was **DENIED** with respect to “trespassing” by agreement of the Parties. (*Id.*; *id.* at 160:14–23). The MIL was **GRANTED** with respect to “copying” or any

variation thereof. (*Id.* at 160:14–23). The Court will act as an active gatekeeper on “copying” issues under the aforementioned MIL rulings. The Court will act in the same way with respect to this MIL.

Defendants’ MIL 6 **Plaintiff should be precluded from introducing or relying on prior art not included in the patent or priority applications.**

The MIL was **GRANTED** with respect to non-expert witnesses. (*Id.* at 167:2–6). The Court again noted that the MIL does not apply to experts whose reports have survived *Daubert* and motion to strike practice. (*Id.* at 166:18–167:1).

Defendants’ MIL 7 **Plaintiff should be precluded from introducing or relying on internal testing not included in the patent or priority applications.**

The MIL was **GRANTED** with respect to non-expert witnesses. (*Id.* at 167:2–6). The Court again noted that the MIL does not apply to experts whose reports have survived *Daubert* motion and motion to strike practice. (*Id.* at 166:18–167:1).

Defendants’ MIL 8 **Preclude any reference to any scientific research that does not involve the Accused Product as defined only by the BLA and other FDA submissions that detailed what is the Accused Product and what can be sold to the public.**

The MIL was **DENIED**. (*Id.* at 170:25–171:15).

Defendants’ MIL 9 **Preclude any argument or reference to any decision by any Defendant not to rely on opinion of counsel and any inference that can be drawn from not obtaining and/or relying on such an opinion.**

The MIL was **GRANTED**. (*Id.* at 172:20–173:11; *id.* at 175:5–8). The Court provided that the application of this MIL would be mutual.

Defendants’ MIL 10 **Preclude testimony, evidence, or argument that Defendants’ lack of written description and enablement arguments are inconsistent with the Court’s claim construction.**

The MIL was **WITHDRAWN**. (*Id.* at 114:18–24; *id.* at 175:11–12).

Defendants' MIL 11 **Preclude testimony, evidence, argument or reference to any pre-trial disputes or rulings over discovery, alleged failure or refusal to provide requested discovery, or any witness or party's discovery conduct.**

The MIL was **DENIED-AS-MOOT**. (*Id.* at 175:13–18).

Defendants' MIL 12 **Preclude testimony, evidence or argument of any reference to the Daiichi Sankyo Japan's pipeline products.**

The MIL was **DENIED** with respect to Seagen's damages expert. (*Id.* at 180:25–181:11).

The Court again noted that the MIL practice should not be used to circumscribe an expert's report that has survived *Daubert* and motion to strike practice. (*Id.*). The Court, however, did **GRANT** the MIL with respect to Seagen's technical expert and any fact witnesses on the separate ground that the information is irrelevant. (*Id.* at 181:12–182:8).

Defendants' MIL 13 **Preclude any reference to a presumption of validity of the patent-in-suit.**

The MIL was **DENIED**. (*Id.* at 183:24–184:10).

Defendants' MIL 14 **Preclude any commentary or reference about the attendance or non-attendance of representatives at trial, decisions to call or not call particular witnesses, or the decisions to call witnesses live, remote, or by deposition.**

The MIL was **GRANTED-BY-AGREEMENT**. (*Id.* at 115:2–8).

Defendants' MIL 15 **Preclude testimony, evidence or argument of any reference to pre-trial disputes over venue, any reference to any motion to transfer or dismiss venue in the Eastern District of Texas on the part of Defendants, or any judicial ruling regarding venue.**


The MIL was **DENIED-AS-MOOT** per the Parties' agreement on Agreed MIL 13. (*Id.* at 184:17).

Defendants' MIL 16 **Preclude any argument based on, or reference to, positively or negatively, the qualifications of the U.S. Patent Office or its examiners,**

except in a manner consistent with the Federal Judiciary Center patent video played to the jury.

The MIL was **DENIED-AS-MOOT** per the Parties' agreement on Agreed MIL 11. (*Id.* at 184:17).

So ORDERED and SIGNED this 15th day of March, 2022.



RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE